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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/803,793

03/18/2004

Erik Buntinx

29248/21

5618

1912

7590

09/02/2008

AMSTER, ROTHSTEIN & EBENSTEIN LLP
90 PARK AVENUE
NEW YORK, NY 10016

EXAMINER

PACKARD, BENJAMIN J

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

09/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/803,793	Applicant(s) BUNTINX, ERIK	
	Examiner Benjamin Packard	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49,50,54,55,72,92 and 93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49,50,54,55,72,92 and 93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1pg (4/4/2008)</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 4/4/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

Claims 49 and 50 were rejected under 35 U.S.C. 103(a) as being unpatentable over Müller (Expert Opinion on Pharmacotherapy, 2002, Vol. 3, No 4, pp. 381-388) in view of PERMAX® prescribing information (http://www.fda.gov/medwatch/safety/2003/permax_PI.pdf, revised October 2, 2003, pp. 1-2).

This rejection is maintained.

Applicants traverse the rejection on the basis that Müller is cautious about combining drugs and that the teaching of Müller contradicts itself where it teaches against the use of butyrophenones. Additionally, Permax ® teaches butyrophenones should not ordinarily be administered concurrently with Permax®.

Examiner responds by pointing out that the instant claims allow for separate or sequential use. Therefore, the claims simply read on the two drugs in separate containers, where both are pharmaceutical preparations. As such, it would be obvious to have both composition in containers for delivery to patients.

Claims 54 and 55 were rejected and **claims 92 and 93** are now rejected under 35 U.S.C. 103(a) as being unpatentable over Müller (Expert Opinion on Pharmacotherapy, 2002, Vol. 3, No 4, pp. 381-388) in view of Silver et al. (Neurology, 1998, Vol. 50, Suppl. 6, pp. S18-S22).

This rejection is maintained with regards to claims 54 and 55 and now applied to claims 92 and 93.

Applicants traverse the rejection based on the argument against Müller above. Additionally, Applicants note Silver teaches the use of dopamine agonists, not use of a dopamine receptor D4 antagonist.

Like above, Examiner responds by pointing out that the instant claims allow for separate or sequential use. Therefore, the claims simply read on the two drugs in separate containers, where both are pharmaceutical preparations. As such, it would be obvious to have both composition in containers for delivery to patients.

Claim 72 were rejected under 35 U.S.C. 103(a) as being unpatentable over Müller (Expert Opinion on Pharmacotherapy, 2002, Vol. 3, No 4, pp. 381-388) in view of Nystrom et al. (US 5,634,213).

This rejection is maintained.

Applicants argue that Müller teaches away from the combination instantly claimed and Nystrom et al is silent as to further combining the disclosed treatment with pipamperone.

Like above, Examiner responds by pointing out that the instant claims allow for separate or sequential use. Therefore, the claims simply read on the two drugs in separate containers, where both are pharmaceutical preparations. As such, it would be obvious to have both composition in containers for delivery to patients.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Benjamin Packard/
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612